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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/003,853	11/02/2001	Ashok V. Joshi	4729US	7449

24247 7590 03/03/2003

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EXAMINER

KONTOS, LINA R

ART UNIT PAPER NUMBER

3763

DATE MAILED: 03/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

MF

Office Action Summary

Application No.

10/003,853

Applicant(s)

JOSHI, ASHOK V.

Examiner

Lina Kontos

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-38 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 35-37 is/are allowed.
- 6) ☒ Claim(s) 1-14, 16, 18-23, 25-29, 31-34 and 38 is/are rejected.
- 7) ☒ Claim(s) 15, 17, 24 and 30 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1.

Claims 22,26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 22 and 26 recite the limitations "said first electrode." There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

2.

Claims 1-4,6-12,14,16 are rejected under 35 U.S.C. 102(b) as being anticipated by Haak et al. in Patent 5,445,606.

Haak et al. teaches a electrotransport device with a current source (column 5, lines 7-8). current controller (column 5, line 7) connected to two electrode assemblies (column 5, line 8) where each electrode assembly has a medicament layer (column 5, line 12 and column 5, lines 21-22) capable of delivering different therapeutic agents. The electrodes may be made of materials such as zinc, silver, or titanium (column 5, lines 41-43) in the form of a foil, powder, etc. (column 5, lines 39, 44-46) and the device as a whole is clearly made of a biocompatible material as it interfaces with human tissue. An ion conducting adhesive layer allows for the transfer of the beneficial agent from the electrode assembly to the tissue of the patient (column 5, lines 31-32). The circuit of the system is completed when in contact with the patient's body, thus allowing the current to transmit the drug to the tissue (column 6, lines 5-7 and lines 15-18 and column 8, lines 25-29).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3.

Claims 5,13,18-23,25-29,31-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Haak in view of Kuhl.

Haak et al. teaches an electrotransport device as described above, wherein the device is used for transdermal iontophoresis.

Kuhl teaches an implantable dosage device (column 1, line 6) with two electrodes (column 2, lines 13-14) and membrane for ion exchange (column 2, lines 12-13). Electric current is required for transport of the medicine from the drug reservoir into the patient (column 2, lines 57-58).

It would have been obvious to one of ordinary skill in the art at the time of the invention to implant the device taught by Haak for the purposes of delivering a therapeutic agent to internal tissue.

4.

Claim 38 is rejected under 35 U.S.C. 103(a) as being unpatentable over Haak in view of Lloyd.

Haak et al. teaches a electrotransport device as described above, wherein the device is used for transdermal iontophoresis.

Lloyd et al. teaches an ocular iontophoretic device with two electrodes (page 2 [0027] and page 3 [0032]), power supply, and means to deliver a medicament (page 2 [0028]).

It would have been obvious to one skilled in the art at the time of the invention to deliver an appropriate drug contained in the reservoir to the ocular region.

Conclusion

5.

Claims 35-37 are allowed.

The following is a statement of reasons for the indication of allowable subject matter:
Independent claim 35 describes an intraocular delivery device that uses the liquid on the surface

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of the subject's conjunctiva to complete a circuit, allowing two electrodes to form a battery, thus driving the drug contained in the system into the patient's conjunctiva.

None of the prior art of record teaches an intraocular drug delivery device placed on the patient's conjunctiva with a semipermeable membrane, means for containing a drug, and two electrodes.

6.

Claims 15,17,24,30 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

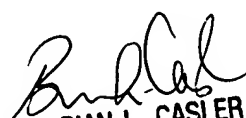
7.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Myers et al. in Patent 5,618,265 teaches an electrically powered iontophoretic delivery device comprising a donor and counter electrode assemblies connected to a power supply (column 4, lines 25-27) and a control circuit (column 5, line 15) via conductive members (column 5, lines 48-49). Both electrode assemblies have means to contain and deliver drugs to the patient (column 8, lines 45-47). The electrodes are manufactured from nonferrous metals capable of oxidization like copper, zinc, and silver (column 6, lines 58-61). An ion conducting adhesive layer allows for the transfer of the beneficial agent from the electrode assembly to the tissue of the patient (column 11, line 26). Placement of the device on patient's tissue completes the circuitry of the system, and current flow from the electrode allows for drug transfer through the adhesive membrane (column 5, lines 42-48).

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Haak et al. Patent 5,857,992 teaches an electrotransport device with two electrodes, each with a semi-permeable membrane (column 1, line 15) and agent reservoirs (column 7, line 3 and column 9, lines 66-67) capable of delivering different drugs (column 10, lines 3-4). The two electrodes are electrically connected to a power supply and a control circuit (Figure 4 and column 9, lines 51-52)


BRIAN L. CASLER
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lina Kontos whose telephone number is (703) 306-4207. The examiner can normally be reached on M-F 8:30-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on (703) 308-3552. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9302 for regular communications and (703) 872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1148.

LRK
February 20, 2003